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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,039	09/23/2002	Ivars Kalvins	81847	9469

23685 7590 09/29/2003

KRIEGSMAN & KRIEGSMAN
665 FRANKLIN STREET
FRAMINGHAM, MA 01702

EXAMINER

SMALL, ANDREA D SOUZA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,039

Applicant(s)

KALVINS ET AL.

Examiner

Andrea D Small

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-11 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

I. Preliminary Matters:

(a) Applicants claim that this application is a 371 of PCT/DE00/03441, which claims priority to GERMANY 199 47 440.0, is acknowledged. However, the priority to GERMANY 199 47 440.0 has not been perfected, as a copy of the certified document has not been received.

(b) Preliminary amendment filed 23 September 2002 has been received and entered into the file.

Claims 1-11 are pending.

II. Rejections:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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(a) Claims 1-4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The R moiety in claim 1 is defined as an organic "residue". This definition renders the aforementioned claims indefinite because, R includes "a single bond" (see claims 2 and 3). The accepted meaning of residue is "a material that remains after any procedure to remove something". Consequently, to an ordinary skilled artisan, the term residue would be understood to include some remainder rather than no remainder at all, which would be the case when R is a 'single bond'. Thus, the term "residue" in claim 1 is confusing and renders the claim indefinite.

(b) Claims 8-11 provide for the use of specific compounds claimed, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

(c) Claim 5 is rejected as being in improper Markush format.

MPEP 2173.05(h): I Markush Groups: Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." *Ex parte Markush*, 1925 C. D. 126 (Comm'r Pat. 1925).

The claim recites compounds according to claim 1, "namely".... The use of this phrase renders the claim ambiguous, as it is unclear whether the Applicant is claiming all the compounds listed in claim 5 or a compound selected from the group of compounds in claim 5. In this regard, the

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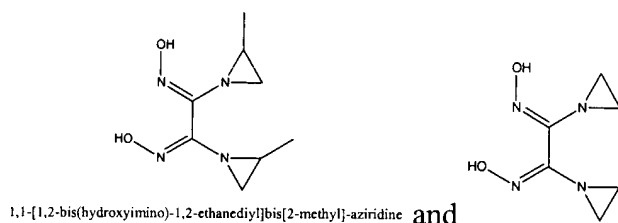
term "namely" is not an acceptable form of alternative expression and thus this claim is in improper Markush format.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ereemeev, et al.

Applicants claims relate to arizidine-1-hydroxymethyl compounds of formula I in claims 1-3 and 7 and a process of preparing these compounds as claimed in claim 6. Ereemeev, et al disclose compounds that anticipate the instantly claimed genus (i) where n is 2, R is a single bond and R1 and R2 are hydrogen, and (ii) where either one of R1 or R2 is methyl, while the other is hydrogen, n is 2 and R is a single bond. See below for re-presentation of the specific species.



See Formula IV and Formula IX in reference on page 369.

Also, the reference discloses the process of preparing these species that anticipates the instant claim 6, wherein dihaloglyoxime is reacted with an appropriately substituted aziridine to produce the species as depicted supra. See scheme 1 in reference on page 369, wherein the R moiety on the dihaloglyoximes is chloro and the R2 and R3 substituents on the aziridine ring as those indicated for Formula IV and IX.

III. Objections:

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Claim 7 is objected to under 37 CFR 1.75 as being a substantial duplicate of any one of claims 1-6. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The compounds of any one of claims 1-6 are drugs. Claim 7 covers that same content as claims 1-6; hence, claim 7 is a substantial duplicate of any one of claims 1-6.

IV. Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrea D. Small whose telephone number is (703) 305-0811.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:30-6:30 PM. The number for accessing the facsimile machine is (703) 746-4984.


Andrea D. Small, Esq.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

September 26, 2003